

The opinion in support of the decision being entered today was not written
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Paper No. 10

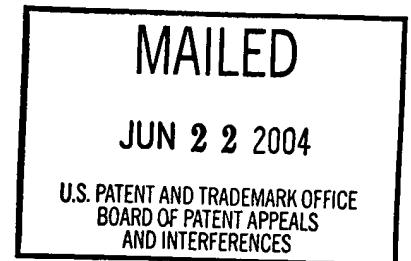
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte GILBERT V. LEVIN

Appeal No. 2004-1391
Application No. 09/811,654

ON BRIEF



Before WINTERS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-7, all of the claims remaining. Claims 1 and 7 are representative and read as follows:

1. A method for promoting cardiovascular health in a mammal in a need of such treatment comprising administering to said mammal an efficacious amount of tagatose to raise the HDL level in the mammal.
7. The method of claim 1 wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers.

The examiner relies on the following reference:

Zehner et al. (Zehner)

5,356,879

Oct. 18, 1994

Claim 7 stands rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description.

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively under 35 U.S.C. § 103 as obvious in view of, Zehner.

We affirm the rejection of claims 1-6. We reverse the rejection of claim 7 and enter a new ground of rejection of that claim.

Background

Tagatose is a known compound that has been used, inter alia, to treat diabetes by "inhibit[ing] the rise in blood sugar associated with the consumption of sugar." Specification, page 1. "A pilot study was conducted at the University of Maryland to investigate the long term effects of D-tagatose in humans with type-2 diabetes. During the course of this study, there was found to be an increase in HDL-cholesterol levels in each of the subjects, both the patients and the controls, treated with tagatose." Id.

Discussion

Claim 1, the only independent claim, is directed to a "method for promoting cardiovascular health in a mammal in need of such treatment," comprising administering tagatose in an amount effective to raise the HDL level in the mammal. An effective amount is "[p]referably . . . in the weight range of 50 mg/kg body weight/day to 1,500 mg/kg body weight/day." Specification, page 2.

1. Description

The examiner rejected claim 7 as lacking an adequate written description in the specification. Claim 7 is directed to the method of claim 1, where the tagatose administered to the patient is "D-tagatose, L-tagatose, or a mixture of the two isomers."

As we understand it, the examiner concluded that this claim was not adequately described because the specification does not provide working examples showing that either L-tagatose or a mixture of D- and L-tagatose was effective to raise HDL levels. See the Examiner's Answer, pages 3-4.

We will reverse this rejection. Whether a claimed method is operative throughout its full scope may raise an issue of enablement, or possibly utility, but it does not pose a problem of written description. Compare In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'") with Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330, 65 USPQ2d 1385, 1397 (Fed. Cir. 2003) ("The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not.").

As Appellant points out, the specification discloses that the claimed method can be practiced by administering "D-tagatose, L-tagatose, or a mixture of the two isomers." Page 2. The examiner has cited no evidence showing that this description does not show possession of the method recited in claim 7. The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

2. Prior art

The examiner rejected claims 1-6 "under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zehner." Examiner's Answer, page 4. The examiner noted that Zehner discloses administration of D-tagatose to mammals at a dosage of 1 g/kg body weight. Id. (citing column 2, lines 45-60).

We agree with the examiner that Zehner anticipates claim 1.¹ Claim 1 is directed to a “method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose to raise the HDL level in the mammal.”

We begin by construing the claim. The body of the claim recites a single manipulative step: administering to a mammal an amount of tagatose effective to raise its HDL level. An effective dose is, e.g., 50-1500 mg/kg body weight/day. Specification, page 2.

The preamble of a claim may or may not add limitations on the claimed method. See, e.g., Bell Communications Research Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) (“[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.”). Here, the preamble states that the method is “for promoting cardiovascular health” and is carried out on “a mammal in need of such treatment.” We conclude that neither of these phrases limits the scope of the method defined in the body of the claim.

First, the preamble recites that the method is “for promoting cardiovascular health.” This language adds nothing to the recitation in the body of the claim that the tagatose is administered in an amount effective to raise HDL levels – raising HDL is the effect that “promot[es] cardiovascular health” as recited in the preamble. The phrase “for

¹ Claims 1-6 stand or fall together. Appeal Brief, page 3. We will consider claim 1 as representative; claims 2-6 will stand or fall with claim 1.

promoting cardiovascular health” therefore does not further limit the claimed method and is irrelevant to claim construction. “If the preamble adds no limitations to those in the body of the claim, the preamble is not itself a claim limitation and is irrelevant to proper construction of the claim.” IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434, 54 USPQ2d 1129, 1137 (Fed. Cir. 2000).

Nor does the preamble’s recitation of “a mammal in need of such treatment” limit the mammal on whom the method is carried out. The specification makes clear that “low levels of HDL are a risk factor in cardiovascular health, as HDLs serve to sweep artery clogging cholesterol from the bloodstream.” Page 1. Nowhere does the specification suggest that the claimed method can or should be carried out only on patients who have a lower-than-normal level of HDL.

The specification does not state, for example, that high levels of HDL are harmful or that treatment with tagatose would be contraindicated if the patient’s HDL level was above a specified amount. Thus, the claim is most reasonably interpreted to read on administration of tagatose even to healthy individuals, since even those individuals would benefit from increased “HDLs serv[ing] to sweep artery clogging cholesterol from the bloodstream.”

We interpret claim 1 to read on administration of tagatose to a mammal, at a dosage that can be, e.g., 50-1500 mg/kg body weight/day. This is the broadest reasonable interpretation of the claim consistent with the specification. See, e.g., In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983).

So interpreted, claim 1 is anticipated by Zehner. Zehner discloses administration of tagatose to rats at a dosage of 1 g/kg body weight (i.e., 1000 mg/kg body weight).

See column 2, lines 47-50. As is apparent from the description of the experiment, the tagatose was administered as a bolus:

Five . . . rats were administered by mouth a water solution of D-tagatose at a dose of 1 g D-tagatose per kg body weight. . . . The blood levels of glucose and insulin were determined initially and at 30, 60, and 90 minutes after administration of the doses.

Column 2, lines 47-56. Thus, Zehner discloses a method comprising administering tagatose to a mammal at a dose of 1000 mg/kg body weight/day. This daily dosage is within the range disclosed in the instant specification to be effective to raise HDL levels. Zehner therefore anticipates claim 1. Claims 2-6 fall with claim 1.

Appellant argues that the preamble's recitation of a "method for promoting cardiovascular health in a mammal" should be treated as a claim limitation, and that "a person practicing the invention disclosed by Zehner et al. would not necessarily and inherently promote cardiovascular health in the individual being treated." Appeal Brief, pages 3-4.

This argument is not persuasive. It is true that Zehner does not disclose that administering D-tagatose at a dosage of 1 g/kg body weight increases HDL levels or promotes cardiovascular health. Based on the evidence of record, however, those skilled in the art would reasonably conclude that increased an HDL level is an inherent effect of administering tagatose at a dosage between 50 and 1500 mg/kg body weight/day. See the instant specification, page 2, first paragraph ("a method for promoting cardiovascular health in a mammal . . . which comprises administering an efficacious amount of tagatose . . . to increase the HDL level") and second paragraph

("Preferably, the tagatose is administered in the weight range of 50 mg/kg body weight/day to 1,500 mg/kg body weight/day.").

It makes no difference, with respect to anticipation, that Zehner did not recognize that the disclosed method produced this effect. See In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."); Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003) ("[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.").

Appellant also argues that Zehner teaches that administration of tagatose reduces the accumulation of glycosylated end products, which is said to slow the aging process. Thus, Appellant argues, the patient being treated in Zehner's method "would not necessarily be a patient in need of treatment for promoting cardiovascular health as required by the appealed claims." Appeal Brief, page 4.

This argument is also unpersuasive. As we have interpreted them, the claims are not limited to treatment of patients who have, for example, an unusually low level of HDLs. Since "HDLs serve to sweep artery clogging cholesterol from the bloodstream," specification, page 1, it is reasonable to conclude that even healthy individuals would benefit from increased HDL levels and therefore are in need of "promoting cardiovascular health." There is no evidence of record that the rats treated in Zehner's experiment were not mammals in need of promoting cardiovascular health.

Finally, Appellant argues that the instantly claimed method differs from the method claimed by Zehner. This argument lacks merit – the instant rejection is based on the working example disclosed by Zehner, not on Zehner's claims. Cf. In re Benno, 768 F.2d 1340, 1346, 226 USPQ 683, 686 (Fed. Cir. 1985) ("The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses . . . that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding.").

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claim 7 is rejected under 35 U.S.C. § 102(b) as anticipated by Zehner. Claim 7 is directed to "[t]he method of claim 1 wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers."

As discussed above, Zehner discloses a method that anticipates instant claim 1. The tagatose administered in the disclosed method was D-tagatose. See column 2, lines 47-50. Thus, the disclosed method also meets the limitations of instant claim 7, and therefore anticipates.

Summary

We reverse the rejection for lack of adequate written description. We affirm the rejection of claims 1-6 as anticipated, and we enter a new rejection of claim 7 on the same basis.

Time Period for Response

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended

effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

(b) Appellant may file a single request for rehearing within two months from the date of the original decision

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

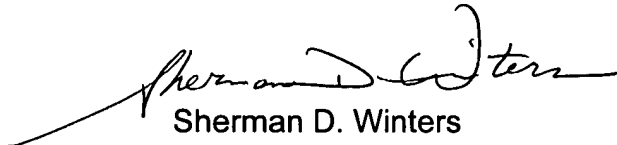
Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be


returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART, REVERSED-IN-PART, 37 CFR § 1.196(b)


Sherman D. Winters
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge


Lora M. Green
Administrative Patent Judge

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